

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Company: American Surgical Device
41917 Osgood Road
Fremont, CA 94539

K955412

MAY 14 1996

Medical Device

Establishment Registration #: pending

Contact: Ms. Liza Burns, Regulatory Consultant

Trade Name: A.S.D. Safety Trocar

Common Name: Surgical Disposable Trocar

Classification Name: Trocar, Gastro-Urology

Classification Code: Gastroenterology and Urology 78FBQ

Device Description:

The **A.S.D. Surgical Trocar** is a single-use, sterile, temporary, disposable device **intended** for use during laparoscopy, to create an entry point for laparoscopic instruments into the abdominal cavity. Surgical instruments of the appropriate size can be safely guided and entered into the abdominal cavity through the cannula.

The **Trocar** consists of: 1) an obturator with a pointed pyramidal tip, 2) a spring-loaded safety shield to cover the tip of the obturator after tissue penetration, 3) a radiolucent cannula (sleeve) with a gasket system to prevent leakage of gas during insertion and withdrawal of instruments 4) an accessory stability thread to help secure the cannula in the body during use. An optional accessory, an obturator adapter is available to be used as a reducer with the 10/11mm system. When the adapter is used, 5 mm instruments are accepted into the 10/11mm trocar.

The A.S.D. Trocar is available in the 10/11mm and 5mm sizes. The size of the trocar corresponds to the size of the instrument that can be entered in the trocar. The sleeve lengths available for the 10/11mm are 100 mm and 150mm; and for the 5mm trocar are 70 mm and 100mm. The stability threads are available in 38 mm and 51 mm lengths.

The A.S.D. Trocar is made of **aluminum, stainless steel, polycarbonate and silicone rubber**.

Indications for use: The **A.S.D. Surgical Trocar** is **intended** for use during vascular and gynecological laparoscopy and other abdominal procedures, to create an entry point for laparoscopic instruments into the abdominal cavity. Surgical instruments of the appropriate size can be safely guided and entered into the abdominal cavity through the cannula.

Contraindications: The A.S.D. Trocar is **not** intended for use when endoscopic techniques are contraindicated.

Substantially Equivalent Devices: 1) The ENDOPATH EP SURGICAL TROCAR
2) The U.S. Surgical SURGIPOINT

Distributed and Manufactured by:

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